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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,328	06/17/2002	Norberto A. Guzman	57430-00006	9218

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,328	GUZMAN, NORBERTO A.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *amendment of September 02, 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/27/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS of 9/23/2005*.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 29 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 2 and 3 of U.S. Patent No.6,406,604 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 2 and 3 together meet all of the limitations of claim 29 of the instant application.

3. Claim 30 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 2 and 3 of U.S.

Patent No.6,406,604 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because a cruciform-configured intersection is implied by the requirement of claim 2 that the separation capillary be perpendicular to the transport capillary.

4. Claim 31 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No.6,406,604 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 meets all of the limitations of claim 31 of the instant application.

5. Claim 32 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No.6,406,604 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 3 meets all of the limitations of claim 32 of the instant application.

6. Claim 33 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No.6,406,604 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 meets all of the limitations of claim 33 of the instant application.

7. Claim 34 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No.6,406,604 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 meets all of the limitations of claim 34 of the instant application.

8. Claim 35 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No.6,406,604 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed overlapping conduit portion overlapping with a portion of the transport conduit between the inlet and outlet is implied the fact that the separation capillary inherently has an inlet end and an outlet end and by the requirement of claim 3 that the analyte concentrator be positioned at the intersection between the transport capillary and the separation capillary.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 31, 33, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Wiktorowicz et al. (US 6,013,1650 ('Wiktorowicz").

Addressing claim 31, Wiktorowicz discloses an electrophoresis apparatus, comprising

a transport conduit (160);

a detector system to identify and characterize first and second analytes of interest (col. 14:17-19; col. 14:43-44; and col. 15:44-65);

first separation conduit means (any of the channels 170 in the second electrophoresis region) for conveying the first analyte of interest concentrated from a sample transported in the transport conduit at a first location of the transport conduit to the detector system (Wiktorowicz discloses performing isoelectric focusing in the transport conduit. See col. 6:2-5. In isoelectric focusing proteins are focused (that is concentrated) at their respective bioelectric points along a pKa gradient. See col. 11:66 – col. 12:8); and

second separation conduit means (any other of the channels 170 that has not been designated as the first separation conduit means) for conveying the second analyte of interest concentrated from a sample transported in the transport conduit at a second location of the transport conduit to the detector system (col. 15:44-57).

Addressing claim 33, Wiktorowicz discloses an electrophoresis apparatus, comprising

a transport channel (160) for transporting a sample;

concentrating means for concentrating a first analyte from the sample as the sample is transported in the transport channel and for concentrating a second analyte from the sample as the sample is transported in the transported channel (Wiktorowicz discloses performing isoelectric focusing in the transport conduit. See col. 6:2-5. In isoelectric focusing proteins are focused (that is concentrated) at their respective bioelectric points along a pKa gradient. See col. 11:66 – col. 12:8);

first separation capillary means for conveying the first concentrated analyte away from the transport channel to a detector system (any of the channels 170 in the second electrophoresis region); and

second separation capillary means (any other of the channels 170 that has not been designated as the first separation conduit means) spaced from the

first separation capillary means for conveying the second concentrated analyte away from the transport channel and to the detector system (col. 15:44-57).

Addressing claim 34, Wiktorowicz discloses an electrophoresis apparatus, comprising

a transport capillary (160) having a first area and a second area (Wiktorowicz discloses performing isoelectric focusing in the transport conduit. See col. 6:2-5. In isoelectric focusing proteins are focused (that is concentrated) at their respective bioelectric points along a pKa gradient. See col. 11:66 – col. 12:8. So the first area and the second area are just areas with different pKas);

a first separation capillary in fluid communication with the transport capillary at the first area (any of the channels 170 in the second electrophoresis region, which intersect the transport capillary);

a second separation capillary in fluid communication with the transport capillary at the second area (any other of the channels 170 that has not been designated as the first separation capillary);

a first analyte concentrator at the first area to concentrate a first analyte from a sample introduced into the transport capillary and allowing the first analyte thereby concentrated to be substantially conveyed to the first separation capillary to an analyte detector zone (the first analyte concentrator will be means to create

an area of desired pKa, such as immobilines or other buffers. See col. 9:4-11. As for a detector zone see col. 15:44-58); and

a second analyte concentrator at eh second area to concentrate a second analyte from the sample and allowing the second analyte thereby concentrated to be subsequently conveyed in the second separation capillary to the analyte detector zone (the second analyte concentrator will be means to create an area of second desired pKa, such as immobilines or other buffers. See col. 9:4-11. As for a detector zone see col. 15:44-58);

11. Claims 29, 30, 32, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al. (US 6,613,525 B2) ("Nelson").

Addressing claim 29, Nelson discloses an electrophoresis apparatus, comprising

a transport capillary (not labeled, but shown in Figure 9. it is the vertical channel directly connected to the sample introduction interface 38 and analyte concentrator 34) into which a sample can be introduced (col. 14:62-63);

a separation capillary (31) having a capillary overlapping portion overlapping at generally a right angle with a portion of the transport capillary (Figure 9);

an analyte concentrator (34) in the capillary overlapping portion to concentrate at least one analyte of interest from the sample introduced into the transport capillary (col. 14:55-56 and col. 4:20-24); and

detector means (37) for identifying and characterizing the at least one analyte of interest delivered thereto by the separation capillary (col. 14:64-65 and col. 12:41-43).

Addressing claim 30, Nelson discloses an electrophoresis apparatus, comprising

a transport conduit (not labeled, but shown in Figure 9. it is the vertical channel directly connected to the sample introduction interface 38 and analyte concentrator 34) into which a sample can be introduced and through which the sample can be conveyed (Figure 9);

a separation conduit (31) in fluid communication with the transport conduit (Figure 9);

a cruciform-configured intersection defined by the intersection of the transport conduit and the separation conduit (Figure 9); and

analyte concentrator means (34) in the intersection for concentrating an analyte of interest from the sample for subsequent conveyance in the separation capillary to a detector (col. 14:55-56; col. 4:20-24; col. 14:64-65; and col. 12:41-43).

Addressing claim 32, Nelson discloses an electrophoresis apparatus, comprising

a transport capillary (not labeled, but shown in Figure 9. it is the vertical channel directly connected to the sample introduction interface 38 and analyte concentrator 34);

a separation capillary (31) in fluid communication with and intersecting the transport capillary (Figure 9); and

affinity means for attracting and concentrating at the intersection of the transport and separation capillaries at least one analyte of interest from a sample introduced into the transport capillary and allowing the concentrated analyte to be subsequently conveyed in the separation capillary to a detector (col. 14:55-56; col. 4:20-24; col. 14:64-65; col. 5:35 – col. 6:67; and col. 12:41-43).

Addressing claim 35, Nelson discloses an electrophoresis apparatus, comprising

a transport conduit (not labeled, but shown in Figure 9. it is the vertical channel directly connected to the sample introduction interface 38 and analyte concentrator 34) having an inlet onto which a sample can be introduced and an outlet (Figure 9);

a separation conduit (31) having an overlapping conduit portion overlapping with a portion of the transport conduit between the inlet and the outlet (Figure 9);

an analyte concentrator (34) in the overlapping conduit portion to concentrate at least one analyte of interest from the sample as the sample passes from the inlet to the outlet (col. 14:55-56 and col. 4:20-24); and

detecting means for identifying and characterizing the at least one analyte of interest concentrated by the analyte concentrator and subsequently conveyed thereto in the separation conduit (col. 14:64-65 and col. 12:41-43).

Status of Objections and Rejections pending since the Office action of March 03, 2005

12. All previous objections and rejections are withdrawn.

International Search Report for PCT/US2004/038401 ('Search Report")

13. US 6,406,604 B1 was cited as an "X" reference against claims 1-3 and as a "Y" reference against claims 4-17, 94-96, and 102-106 in the Search Report. There were only 28 claims in the original disclosure of the instant application. Only claims 29-35 are

currently pending. US 6,406,604 B1 has been used above to reject all of the pending claims in double-patenting rejections.

14. US 6,613,525 B2 was cited as a "Y" reference against claims 4-30 in the Search Report. There were only 28 claims in the original disclosure of the instant application. Only claims 29-35 are currently pending. US 6,613,525 B2 has been used above to reject claims 29, 30, 32, and 35 under 35 U.S.C. 102(e).

15. US 2002/0042125 A1 was cited as a "Y" reference against claims 18-30 and as an "X" reference against claims 69-71 and 40-45 in the Search Report. There were only 28 claims in the original disclosure of the instant application. Only claims 29-35 are currently pending. All of the claims of the instant application are directed to electrophoresis apparatuses. US 2002/0042125 A1 only broadly recites using electrophoresis as a motive force for moving sample through the channels. See paragraphs [0066] and [0135]. Moreover, in US 2002/0042125 A1 the analyte concentrator (122, 177) is not located at a capillary intersection or in overlapping portions of two capillaries. See Figures 2 and 18 and paragraphs [0049] and [0202].

16. WO 03/012398 A1 was cited as an "X" reference against claims 31, 33, 34, and 50-53 and a "Y" reference against claims 32, 35-39, and 54-91 in the Search Report. There were only 28 claims in the original disclosure of the instant application. Only

claims 29-35 are currently pending. WO 03/012398 A1 was published February 13, 2003. It claims priority from U.S. provisional application no. 60/309,815, filed August 03, 2001. However, the instant application was filed on June 17, 2002 is a continuation of U.S. Application no. 09/436,186, which was filed on November 08, 1999. Thus, WO 03/012398 A1 does not qualify as prior art against the instant application at least because of its earlier priority date.

17. Guzman (*Electrophoresis* 2003 24, 3718-3727) was cited as an "X" reference against claims 46-49 and as a "Y" reference against claims 32, 35-39, and 54-91 in the Search Report. Guzman (*Electrophoresis* 2003 24, 3718-3727) was published in November 2003. The instant application was filed on June 17, 2002 and is a continuation of U.S. Application no. 09/436,186, which was filed on November 08, 1999. Thus, WO 03/012398 A1 does not qualify as prior art against the instant application. Additionally, Norberto Guzman is the sole author of Guzman (*Electrophoresis* 2003 24, 3718-3727) and the sole inventor of the instant application. Thus, Guzman (*Electrophoresis* 2003 24, 3718-3727) is not by "another."

18. WO 98/23950 A was cited as an "X" reference against claims 92, 93, 97-101 and as a "Y" reference against claims 94-96 and 102-106 in the Search Report. There were only 28 claims in the original disclosure of the instant application. Only claims 29-35 are currently pending. WO 98/23950 A is directed to computer-assisted methods for

identifying and isolating subsets of biomolecules separated in an electrophoresis slab gel. See the abstract; page 8:8-16; and Figure 3. It does not disclose capillaries or microchannels.

Final Rejection

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Nogueróla
Primary Examiner
AU 1753
November 2, 2005